UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|--------------------------------------|-----------------------|---------------------|------------------|
| 10/695,632 | 10/27/2003 Brian G. Connor | | HYZ-038US01RCE | 6413 |
| | 7590 12/23/200 E ENGLISH, LLP BOS | EXAMINER | | |
| 265 Franklin St | reet | DOWE, KATHERINE MARIE | | |
| Boston, MA 02 | 110 | | ART UNIT | PAPER NUMBER |
| | | | 3734 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/23/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Astion Communication | | Applic | ication No. Applicant(s) | | | | |
|---|---|---|---|--|---------------|--|--|
| | | 10/695 | ,632 | CONNOR ET AL. | CONNOR ET AL. | | |
| Office Action Summary | | | ner | Art Unit | | | |
| | | KATHE | RINE M. DOWE | 3734 | | | |
| Period for | The MAILING DATE of this communicate Reply | ation appears on | the cover sheet with the | correspondence ac | ddress | | |
| A SHOI WHICH - Extensi after SI - If NO pr - Failure Any rep | RTENED STATUTORY PERIOD FOR IEVER IS LONGER, FROM THE MA ons of time may be available under the provisions of X (6) MONTHS from the mailing date of this community of the properties of the second for reply is specified above, the maximum status to reply within the set or extended period for reply with y received by the Office later than three months after patent term adjustment. See 37 CFR 1.704(b). | ILING DATE OF 37 CFR 1.136(a). In no ication. tory period will apply an II, by statute, cause the | THIS COMMUNICATION event, however, may a reply be to divid expire SIX (6) MONTHS from application to become ABANDON | DN. imely filed m the mailing date of this o IED (35 U.S.C. § 133). | · | | |
| Status | | | | | | | |
| 2a)⊠ T 3)□ S | desponsive to communication(s) filed his action is FINAL . 2b ince this application is in condition followed in accordance with the practice |)∭ This action i r allowance exce | s non-final. pt for formal matters, p | | e merits is | | |
| Dispositio | n of Claims | | | | | | |
| 4a 5)□ C 6)⊠ C 7)□ C | Elaim(s) <u>1-3,6,8,11-17,20-22,24-26,3</u> ; a) Of the above claim(s) <u>44-52</u> is/are Elaim(s) is/are allowed. Elaim(s) <u>1-3,6,8,11-17,20-22,24-26,3</u> ; Elaim(s) is/are objected to. Elaim(s) are subject to restriction | withdrawn from 0 1,39-43,55,56,59 | consideration. | | ation. | | |
| Applicatio | n Papers | | | | | | |
| 10)□ TI A R | ne specification is objected to by the ne drawing(s) filed on is/are: a pplicant may not request that any objective placement drawing sheet(s) including the oath or declaration is objected to be | a) accepted or on to the drawing(s ne correction is req | s) be held in abeyance. So uired if the drawing(s) is o | ee 37 CFR 1.85(a). bjected to. See 37 C | , , | | |
| Priority un | der 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 2) Notice | s) of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO tion Disclosure Statement(s) (PTO/SB/08) | D-948) | 4) Interview Summar Paper No(s)/Mail I 5) Notice of Informal | Date | | | |
| Paper N | lo(s)/Mail Date | | 6) | | | | |

Application/Control Number: 10/695,632 Page 2

Art Unit: 3734

DETAILED ACTION

The following is a complete response to the amendment filed September 23,
 2009.

2. Claims 1-3, 6, 8, 11-17, 20-22, 24-26, 31, 39-43, 55, 56, 59, 60, 68, and 69 are currently under examination, with claims 44-52 withdrawn from consideration.

Claim Objections

3. Claims 44-52 are objected to because of the following informalities: The claim headings recite the claims are "previously presented". However, the claims have been withdrawn from consideration without traverse, as noted on page 1 of Applicant's remarks filed September 23, 2009. Appropriate correction is required.

Claim Rejections - 35 USC § 103

- 4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5. Claims 1-3, 6, 8, 11-17, 20-22, 24-26, 31, 39-43, 55, 56, 59, 60, 68, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drasler et al. (US 5,496,267, hereinafter "Drasler") in view of Plechinger et al. (US 5,318,518, hereinafter "Plechinger"). Regarding claims 1-3, 6, 8, 25, 26, 31, 43, 55, 56, 59, 60, 68, and 69, Drasler discloses the invention substantially as claimed including a surgical cutting instrument comprising a nozzle (122) located at the distal end of the instrument that is shaped to form a liquid jet (124), a pressure lumen (114) configured to convey a flow of

Application/Control Number: 10/695,632

Page 3

Art Unit: 3734

liquid to the nozzle, and an evacuation lumen (128) located between the nozzle and the proximal end of the instrument in the axial direction, comprising a jet-receiving opening (distal end of 128) located opposite the nozzle to receive at least a portion of the liquid jet emitted from the nozzle and convey a flow of liquid away from the jet receiving opening (Fig 3a). The instrument defines a cup-shaped tissue receptacle configured to contain excised tissue (area defined by 126, 114, and 122 and shown enclosing target 120 in Fig 3A; see annotated Figure 3A below) and may be considered a curette. However, Drasler does not disclose a non-liquid jet tissue-excision component. Plechinger discloses a similar surgical cutting instrument comprising a nozzle (14) for delivering a liquid jet and an evacuation lumen (18) located opposite the nozzle. Plechinger teaches the device may additionally comprise a non-liquid jet tissue-excision component (50), or cutting edge, on the distal end of the nozzle (Fig 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Drasler such that the distal end of the nozzle (124), which is substantially opposite the jet-receiving opening (distal end of 128), comprised a non-liquid jet tissue-excision component with a sharpened edge that extends radially outward from an axial center of the nozzle to a radial periphery in view of Plechinger. With such a modification, the non-liquid jet tissue-excision component can excise large pieces of tissue enabling the liquid jet to more easily emulsify and remove the tissue.

Regarding claims 11-17, the pressure lumen is configured to enable it to convey a high-pressure liquid at a pressure of at least 30,000 psig (col 4, II 51-67).

Application/Control Number: 10/695,632 Page 4

Art Unit: 3734

Regarding claims 20 and 24, the evacuation lumen (128) is shaped and positioned to enable it to remove at least a portion of excised tissue and essentially all of the liquid comprising the liquid jet, without the need for external suction (col 6, II 17-21).

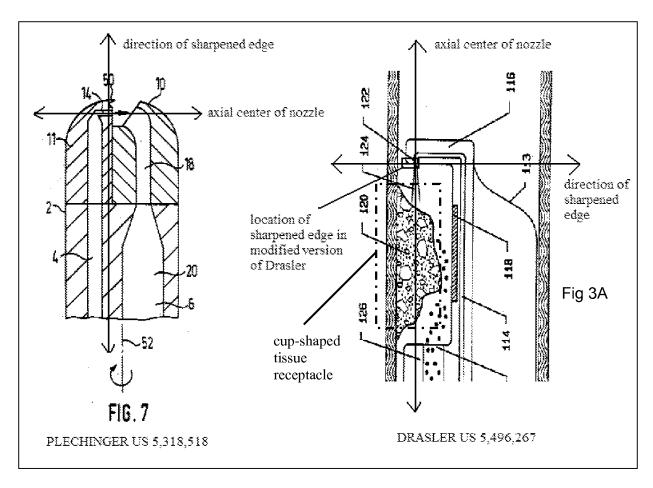
Regarding claims 21 and 22, the distal end of the device is capable of being inserted into the spine of a patient.

Regarding claims 39-42, Drasler does not disclose if the instrument is disposable. However, it is well known in the art to make medical devices completely or partially disposable to ensure sterility and remove the risk of cross-contamination between patients.

Application/Control Number: 10/695,632

Page 5

Art Unit: 3734



Response to Arguments

- 6. Applicant's arguments filed September 23, 2009 have been fully considered but they are not persuasive.
- 7. Applicant argues neither Drasler nor Plechinger, independently or in combination, provides for a non-liquid jet tissue-excision component that has sharpened edges perpendicular to the liquid jet. Furthermore, Applicant asserts the cutting edge (50) of Plechinger is directed parallel to the axial center of the nozzle (14). The Examiner respectfully disagrees and directs Applicant to the annotated versions of Plechinger's Figure 7 and Drasler's Figure 3A above. Plechinger clearly discloses the cutting edge

Application/Control Number: 10/695,632

Art Unit: 3734

(50) is directed perpendicular to the axial center of the nozzle (14), which is in line with the direction of the liquid jet. Furthermore, when Drasler is modified in view of Plechinger, it is obvious the cutting edge would be placed in an analogous position and thus would extend from the nozzle (122) to the outer edge of the instrument in a direction perpendicular to the axial center of the nozzle (122), which is in line with the direction of the liquid jet.

Page 6

- 8. Regarding claims 55, 56, 59, and 60, Applicant additionally argues Drasler does not disclose a cup-shaped tissue receptacle. The Examiner respectfully disagrees and notes the tissue receptacle of Drasler (area bounded by elements 126, 114, and 122 and shown enclosing target 120 in Fig 3A; see annotated version of Figure 3A above) may be interpreted as being "cup-shaped".
- 9. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Plechinger teaches a non-liquid jet tissue excision component (50) adjacent a nozzle (14) to cut target tissue. Thus, it would have been obvious to modify the device of Drasler such the device comprised a non-liquid jet tissue excision component adjacent the nozzle (122)

Art Unit: 3734

to cut target tissue that is not excised by the liquid jet or is difficult to excise by the liquid jet to improve the excision capability of the instrument.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/695,632 Page 8

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe December 11, 2009

/K. M. D./ Examiner, Art Unit 3734

/Todd E Manahan/ Supervisory Patent Examiner, Art Unit 3734